



AMENDMENTS TO THE CLAIMS:

Please amend claims 1-4, 10, 11, 15, 17, 35, and cancel claim 16 without prejudice or disclaimer as follows. This listing of claims replaces all prior versions, and listings of claims, in the application.

LISTING OF CLAIMS:

1. (Currently Amended) A combination, comprising:
a kit test system for detecting ~~the presence of~~ a fetal-restricted antigen or estriol in a sample, wherein the detected fetal-restricted antigen or estriol is indicative of a risk of preterm delivery; and
a progesterone-related agent or an omega-3 fatty acid.
2. (Currently Amended) The combination of claim 1, wherein the kit test system comprises an antibody that specifically binds to a fetal restricted antigen or an antibody that specifically binds to estriol.
3. (Currently Amended) The combination of claim 1, wherein the kit test system comprises an immunoassay test strip to detect a fetal restricted antigen or estriol in a sample.
4. (Currently Amended) The combination of claim 1, wherein the sample ~~contains a~~ is body fluid or a swab of the posterior fornix, the cervical canal, the ectocervix and/or the external cervical os.
5. (Original) The combination of claim 1, wherein the progesterone-related agent is a progesterone.
6. (Original) The combination of claim 1, wherein the progesterone-related agent is 17- α -hydroxyprogesterone or 17- α -hydroxyprogesterone caproate.
7. (Original) The combination of claim 1, wherein the omega-3 fatty acid is docosahexaenoic acid.
8. (Original) A combination for screening and treating a subject, comprising:
 - a) a solid support, comprising an anti-(preterm delivery marker) antibody; and
 - b) a progestational agent.
9. (Original) The combination of claim 8, wherein the anti-(preterm delivery marker) antibody is selected from the group consisting of an anti-(fetal restricted antigen) antibody, an anti-(fetal restricted antigen class) antibody, and an anti-estriol antibody.
10. (Currently amended) The combination of claim 8, further comprising a second anti-(fetal restricted antigen) antibody directed to the same antigen.

11. (Currently amended) The combination of claim 10 ~~8~~, ~~wherein the second antibody is selected from the group consisting of an anti-(fetal restricted antigen) antibody, an anti-(fetal restricted antigen class) antibody, an anti-estriol antibody, and an anti-(insulin-like growth factor binding protein one) antibody~~ further comprising one or more anti-(membrane rupture marker) antibodies.

12. (Original) The combination of claim 8, wherein the progestational agent is a progesterone-related agent or omega-3 fatty acid or a derivative thereof.

13. (Original) The combination of claim 8, wherein the progestational agent is 17- α -hydroxyprogesterone or 17- α -hydroxyprogesterone caproate.

14. (Original) The combination of claim 8, wherein the progestational agent comprises docosahexaenoic acid.

15. (Currently amended) The combination of claim 8, ~~further~~ comprising three or more antibodies, wherein the antibodies ~~are anti-preterm delivery marker antibodies~~ include an anti-fibronectin antibody, an anti-estriol antibody, and an anti-(insulin-like growth factor binding protein one) antibody.

16. (Cancelled).

17. (Currently amended) A method of screening and treating a subject, comprising:
(a) monitoring the level of a marker of preterm or imminent delivery in a body fluid sample from a subject following about 20 weeks of gestation; and

(b) if the level is indicative of a risk for preterm or imminent delivery, administering a progestational agent, whereby delivery is delayed, wherein the progestational agent is selected from the group consisting of a naturally or synthetically produced omega-3 fatty acid, a naturally or synthetically produced hormone normally secreted by the corpus luteum, placenta, or adrenal cortex, and derivatives and mixtures thereof.

18. (Original) The method of claim 17, wherein the level is equal to or above a predetermined level.

19. (Original) The method of claim 17, wherein the level is equal to or below a predetermined level.

20. (Currently amended) The method of claim 17, wherein the marker is unconjugated estriol.

21. (Previously presented) The method of claim 17, wherein the marker is the ratio of estriol to progesterone.

22. (Original) The method of claim 17, wherein the marker is a fetal restricted antigen.

23. (Original) The method of claim 22, wherein the fetal restricted antigen is fetal fibronectin.

24. (Original) The method of claim 17, wherein the progestational agent is selected from the group consisting of dydrogesterone; ethynodiol diacetate; hydroxyprogesterone caproate; medroxyprogesterone acetate; norethindrone; norethindrone acetate; norethynodrel; norgestrel; megestrol acetate; gestodene; desogestrel; cingestol; lynestrenol; quingestanol acetate; levonorgestrel; 3-ketodesogestrel; norgestimate; osaterone; cyproterone acetate; trimegestone; dienogest; drospirenone; nomegestrol; (17-deacetyl)norgestimnate; 19-norprogesterone; melengestrol; ethisterone; medroxyprogesterone acetate; 17- α -hydroxyprogesterone; dimethisterone; ethinylestrenol; demegestone; promegestone; chlormadinone; pregn-4-ene-3,20-dione (progesterone); 19-nor-pregn-4-ene-3,20-dione; 17-hydroxy-19-nor-17 α -pregn-5(10)-ene-20-yn-3-one; dl-11 α -ethyl-17-ethinyl-17- α -hydroxygon-4-ene-3-one; 17-ethynyl-17-hydroxy-5(10)-estren-3-one; 17 α -ethynyl-19-norestosterone; 6-chloro-17-hydroxypregna-4,6-diene-3,20-dione; 17 α -hydroxy-6 α -methyl-17(-1-propynyl)-androst-4-ene-3-one; 9 α ,10 α -pregna-4,6-diene-3,20-dione; 17-hydroxy-17 α -pregn-4-en-20-yne-3-one; 19-nor-17 α -preg-4-en-20-yen-3,17-diol; 17-hydroxy-pregn-4-ene-3,20-dione; 1-7-hydroxy-6 α -methylpregn-4-ene-3,20-dione, 17- α -hydroxyprogesterone caproate, and mixtures thereof.

25. (Original) The method of claim 24, wherein the progestational agent is 17- α -hydroxyprogesterone or 17- α -hydroxyprogesterone caproate.

26. (Original) A method of screening and treating a subject, comprising:

- (a) monitoring the level of a first marker and a second marker of preterm or imminent delivery in a body fluid sample from a subject;
- (b) if the level of the first marker is indicative of a risk for preterm or imminent delivery, evaluating the level of the second marker; and

(c) if the level of the second marker is indicative of a risk for preterm or imminent delivery, administering a progestational agent, whereby delivery is delayed.

27. (Original) The method of claim 26, wherein the first marker is a fetal restricted antigen and the second marker is estriol.

28. (Original) The method of claim 27, wherein the fetal restricted antigen is fetal fibronectin.

29. (Previously presented) The method of claim 27, wherein the estriol is unconjugated estriol.

30. (Original) The method of claim 17, further comprising the steps of:
monitoring the level of a marker for membrane rupture; and
if the level is not indicative of membrane rupture, administering a progestational agent, whereby delivery is delayed.

31. (Original) The method of claim 30, wherein the marker of preterm delivery is selected from the group consisting of estriol and a fetal restricted antigen.

32. (Original) The method of claim 30, wherein the marker of preterm delivery is unconjugated estriol.

33. (Original) The method of claim 30, wherein the marker of preterm delivery is fetal fibronectin.

34. (Original) The method of claim 30, wherein the marker of membrane rupture is insulin-like growth factor binding protein one.

35. (Currently amended) A method of screening and treating a subject, comprising:
a) detecting a fetal restricted antigen in a sample from a subject and assessing whether the level of fetal restricted antigen is indicative of a risk of preterm or imminent delivery; and

b) if the level of fetal restricted antigen is indicative of the risk, detecting estriol in a sample from a subject and assessing whether the level of estriol is indicative of a risk of preterm or imminent delivery;

c) if the level of estriol is indicative of the risk, assessing the level of a marker for membrane rupture; and

d) if the level of the marker for membrane rupture is not indicative of membrane rupture, administering a therapeutically effective amount of a progestational agent to the subject, whereby delivery is delayed.

36. (Original) The method of claim 35, wherein the sample contains a body fluid or a swab of the posterior fornix, the cervical canal, the ectocervix and/or the external cervical os.

37. (Original) The method of claim 35, wherein a level indicative of the risk is above a minimum threshold amount.

38. (Original) The method of claim 35, wherein a level indicative of the risk is below a maximum threshold amount.

39. (Original) The method of claim 35, wherein the progestational agent is administered after the start of fetal organogenesis.

40. (Previously presented) The method of claim 35 wherein the sample is obtained after about 12 weeks gestation.

41. (Original) The method of claim 35, wherein the sample is obtained after about 16 weeks gestation.

42. (Original) The method of claim 35 wherein the sample is obtained after about 20 weeks gestation.

43. (Original) The method of claim 35, wherein the administration of the progestational agent is stopped at about 36 weeks of gestation or at the onset of spontaneous labor.

44. (Original) The method of claim 35, wherein the fetal restricted antigen is fetal fibronectin.

45. (Original) The method of claim 35, wherein the progestational agent comprises at least one omega-3 fatty acid or a derivative thereof.

46. (Original) The method of claim 45, wherein the progestational agent comprises docosahexaenoic acid.

47. (Original) The method of claim 35, wherein the progestational agent is a progesterone-related agent.

48. (Original) The method of claim 47, wherein the progesterone-related agent is 17- α -hydroxyprogesterone or 17- α -hydroxyprogesterone caproate.

49. (Original) The method of claim 35, wherein the therapeutically effective amount of the progestational agent comprises at least about 100 mg/week of the progestational agent.

50. (Original) The method of claim 35, wherein the progestational agent is administered orally, by intramuscular injection, transdermally, or intranasally.

51. (Original) The method of claim 35, further comprising the step of:

if the level of fetal restricted antigen is not indicative of a risk of preterm or imminent delivery, repeating at intervals at least one day apart the steps of detecting the fetal restricted antigen in the sample and assessing whether the level of fetal restricted antigen is indicative of the risk; wherein

if the level of fetal restricted antigen is indicative of the risk, administering a progestational agent to the subject, whereby delivery is delayed.

52. (Original) The method of claim 44, wherein the level indicative of the risk is a minimum threshold value of about 50 ng/mL.

53. (Original) The method of claim 44, wherein the sample is obtained from the posterior fornix.

54. (Original) The method of claim 44, wherein the sample is obtained from the cervical os.

55. (Original) The method of claim 44, wherein the level of fetal fibronectin is determined by the steps of:

- a) contacting the sample with an anti-(fetal fibronectin) antibody for a time sufficient to permit antigen-antibody binding to occur;
- b) contacting the sample with an insoluble support, to which anti-fibronectin antibody is adhered, for a time sufficient to permit antigen-antibody binding to occur; and
- c) detecting anti-(fetal fibronectin) antibody on the insoluble support.

56. (Original) The method of claim 55, wherein material from the sample is contacted with the insoluble support in a region of the insoluble support that contains mobilizable anti-(fetal fibronectin) antibody.

57. (Previously presented) The method of claim 55, wherein the anti-(fetal fibronectin) antibody is conjugated to a physically detectable label.

58. (Original) The method of claim 55, wherein the step of detecting anti-(fetal fibronectin) antibody comprises the steps of:

- a) contacting the insoluble support with a labelled antibody which binds selectively with the anti-(fetal fibronectin) antibody; and
- b) detecting the label on the insoluble support.

59. (Original) The method of claim 44, wherein the subject is a preterm subject.

60. (Original) The method of claim 59, wherein the subject is at risk for preterm delivery.

61. (Original) The method of claim 44, wherein the level of fetal fibronectin is determined by the steps of:

- a) contacting the sample with an anti-fibronectin antibody for a time sufficient to permit antigen-antibody binding to occur; and
- b) detecting formation of an antibody-antigen complex.

62. (Original) The method of claim 61, wherein the step of detecting formation of an antibody-antigen complex further comprises the steps of:

- c) contacting the sample with an insoluble support comprising an immobilized anti-(fetal fibronectin) antibody under conditions, whereby fetal fibronectin in the sample binds to the antibody; and
- d) detecting the anti-fibronectin antibody on the insoluble support.

63. (Original) The method of claim 61, wherein the anti-fibronectin antibody comprises a detectable label.

64. (Original) The method of claim 62, wherein the step of detecting the anti-fibronectin antibody comprises the steps of:

- e) contacting the insoluble support with a labeled antibody that binds selectively with the anti-fibronectin antibody; and
- f) detecting the label on the insoluble support.